UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

MEMORANDUM

DATE: December 5, 2011

SUBJECT: Efficacy Review for STERIPLEX SD (Part A);
EPA File Symbol 84545-RR;
DP Barcode: D393485

FROM: Lorilyn M. Montford 12/8/11
Efficacy Evaluation Team
Antimicrobials Division (7510P)

THRU: Dr. Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P) 12/8/11

TO: Marshall Swindell, PM 33/Abigail Downs
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: sBioMed, LLC
1272 South 1380 West
Orem, UT 84058

Formulation From Label:

Active Ingredient(s)	% by wt.
Silver	0.015%
Inert Ingredient(s)	99.985%
Total	100.000%

I BACKGROUND

The product, STERIPLEX SD Part A (EPA File Symbol 84545-RR), is a new product. STERIPLEX SD Part A is one part of a two-component system. STERIPLEX SD Part A is mixed with an activator (i.e., STERIPLEX SD Part B Activator Solution) prior to use. The activated product is for use as a disinfectant (sporicide, bactericide, fungicide, tuberculocide, virucide), sanitizer, mildewcide, and deodorizer on hard, non-porous surfaces in institutional, industrial, food preparation, food processing, animal care, and hospital or medical environments. The label states that the product is effective as a disinfectant in the presence of 5% serum contamination. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 5512t; and MICROBIOTEST, located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant's representative (dated August 4, 2011), EPA Form 8570-4 (Confidential Statement of Formula), twenty seven studies (MRID 485701-03 through 48570t-29), Statements of No Data Confidentiality Claims for all twenty seven studies, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: activity centers, appliances, arm rests, athletic headgear, athletic helmets, athletic mats, barber and salon instruments and tools, bassinets, bathtubs, bed railings, benches, cabinets, cages, car seats, carts, chairs, changing tables, computer keyboards, cribs, counters, diaper pails, doorknobs and handles, drawer pulls, examination tables, exercise equipment, faucet fixtures, floors, furniture, goggles, gymnastic mats, handles, hospital equipment (e.g., autoclaves, baskets, bed pans, blood glucose monitors, gurneys, incubators, IV poles, mammography equipment, patient monitoring equipment, physical therapy equipment, respiratory equipment, stethoscopes, stretchers, ultrasound transducers and probes, walkers, wheelchairs), instruments, light switch covers, lighting fixtures, kennel runs, mirrors, pails, pans, personal protective safety equipment, play pens, play sets, railings, reception desks, remote controls, scales, sealed electronics, seats, shower stalls, sinks, stools, strollers, tables, telephones, toilet bowls and seats, toy boxes, toys, training tables, trash cans, trays, urinals, utensils, walls, window sills, and wrestling mats. The product is designed for sanitizing hard, non-porous, food-contact surfaces, including: beer fermentation tanks, beverage dispensing equipment, blenders, bottles, bottling or premix dispensing equipment, collators, coolers, conveyors, countertops, dairy equipment, dishes, evaporators, fillers, filters, food processing equipment, food utensils, glasses, holding tanks, pasteurizers, peelers, pipelines, refrigerated storage and display equipment, sink tops, silverware, slicers, saws, tableware, tanks, and vats. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: Corian, Formica, glass, glazed ceramic, glazed enamel, glazed porcelain, glazed tile, laminated surfaces, metal (e.g., chrome, stainless steel), plastic (e.g., acrylic, high-density polyethylene, low-density polyethylene, polypropylene, vinyl), Plexiglas, sealed fiberglass, sealed finished woodwork, sealed granite, sealed limestone, sealed marble, sealed slate, sealed stone, sealed terra cotta, and sealed terrazzo, silicone rubber, and vinyl rubber. Directions on the proposed label provide the following information regarding preparation and use of the product:

As a disinfectant: Activate the product prior to use by pouring the contents of the Part B bottle into the Part A bottle, and then shaking the combined solution for approximately 15 seconds. Apply the activated product using a cloth, mop, sponge, or mechanical coarse spray device, or by total immersion until the surface is thoroughly wet. Treated surfaces must remain wet for 5 minutes. Allow to air dry. Gross soil must be removed prior to disinfecting.

As a sanitizer on food contact surfaces: Activate the product prior to use by pouring the contents of the Part B bottle into the Part A bottle, and then shaking the combined solution for approximately 15 seconds. Apply activated product using a cloth, mop, sponge, brush, or mechanical coarse spray device, or by total immersion until the surface is thoroughly wet. Treated surfaces must remain wet for 30 seconds. Allow to drain and air dry. Pre-clean equipment prior to sanitizing.

As a disinfectant against *Clostridium difficile* spores: Fecal matter/waste and gross soil must be thoroughly cleaned from surfaces/objects before disinfection. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. To minimize spreading of spores, surfaces in patient rooms are to be cleaned in an appropriate manner such as clockwise or counter-clockwise for horizontal surfaces, and top to bottom on vertical surfaces. Apply the activated product using a cloth, mop, sponge, or mechanical coarse spray device until the surface is thoroughly wet. Treated surfaces must remain wet for 5 minutes. Allow to air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the

specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Disinfectants for Use as Tuberculocides (Using the AOAC Tuberculocidal Activity of Disinfectants Test Method)

Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. Certain chemical classes (i.e., glutaraldehyde and quaternary ammonium compounds) are required to undergo validation testing in addition to basic testing. Products that are formulated with other chemical groups do not require validation testing. When using the existing or modified AOAC Tuberculocidal Activity Test Methods, 10 carriers for each of 2 samples, representing 2 different product lots, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). Killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of 2 additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When

cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces)

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

Sporicidal Disinfectant against *Clostridium difficile*

The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following four test methods: Most recent version (2006) of AOAC Method 966.04 (For the AOAC Method 966.04, testing should be conducted with two separate batches of product, using 30 carriers per batch for testing of registered sterilants; and three separate batches of product (one of which is at least 60 days old), using 60 carriers per batch for testing of hospital disinfectants. For the quantitative tests, the carrier number specified in the test method should be used): AOAC Sporicidal Activity of Disinfectants Test, Method I for *Clostridium sporogenes*; AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces; or ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the

Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The following toxigenic strains of *Clostridium difficile* may be used for testing: ATCC 700792, ATCC 43598, or ATCC 43599. All products must carry a pre-cleaning step, thus no organic soil should be added to the spore inoculum. Results must show a minimum 6 log reduction of viable spores in t0 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

Sterilizers

The AOAC Sporicidal Test is required for substantiating sterilizing claims. The following information applies to all products represented as sporicidal or sterilizing agents. Sixty carriers, representing each of 2 types of surfaces (porcelain penicylinders and silk suture loops), must be tested against spores of both *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on 3 product samples representing 3 different product lots, one of which is at least 60 days old (240 carriers per sample; a total of 720 carriers). Any sterilizing agent (liquid, vapor, or gas) that is recommended for use in a specific device must be tested by the AOAC Sporicidal Test in that specific device and according to the directions for use. Killing on all of the 720 carriers is required; no failures are permitted. Data to support sterilizing claims must be confirmed by tests conducted by a second, independent laboratory of the applicant's choice (other than the laboratory that developed the original data). The following minimal confirmatory data must be developed on one sample of the product: Thirty carriers with each of the 2 types of surfaces (silk suture loops and porcelain penicylinders) against spores of both *Bacillus subtilis* and *Clostridium sporogenes* (a total of 120 carriers) by the AOAC Sporicidal Test. These Agency standards are presented in DIS/TSS-9.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 485701-03 "Virucidal Efficacy Test SARS-Associated Coronavirus" for Steriplex SD, by Helen Christina. Study conducted at MICROBIOTEST. Study completion date – April 7, 2011. Laboratory Project Identification Number 686-149.

This study was conducted against SARS-Associated coronavirus (obtained from Zeptometrix), using Vero E6 cells (ATCC CRL-1586) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and S202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - SARS-Associated Coronavirus," dated February 25, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil

load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 and 5% fetal bovine serum. Vero E6 cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 4-9 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

2. MRID 485701-04 "Virucidal Efficacy Test Respiratory Syncytial Virus" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – April 26, 2011. Laboratory Project Identification Number 686-150.

This study was conducted against Respiratory syncytial virus (ATCC VR-26), using HeLa cells (ATCC CCL-2) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Respiratory Syncytial Virus" dated February 25, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 27 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in DMEM and 5% fetal bovine serum. HeLa cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 5-18 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

3. MRID 485701-05 "Virucidal Efficacy Test Poliovirus type 1" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – March 25, 2011. Laboratory Project Identification Number 686-157.

This study was conducted against Poliovirus type 1 (ATCC VR-1562), using MA-104 cells (obtained from Charles River Laboratories) as the host system. Two lots of Steriplex SD

were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 825009230t and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Poliovirus Type 1," dated February 9, 201t (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes and 7 minutes at 21°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 and 5% fetal bovine serum. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 6-9 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

4. MRID 485701-06 "Virucidal Efficacy Test Murine Norovirus (Surrogate for Human Norovirus)" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – March 11, 2011. Laboratory Project Identification Number 686-139.

This study was conducted against Murine norovirus (obtained from Yale University), using RAW 264.7 cells (ATCC TIB-7t) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-1t0182 and 01-t10183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Murine Norovirus (Surrogate for Human Norovirus)," dated February 9, 20t1 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in Dulbecco's Modified Eagle Medium and 5% fetal bovine serum. RAW 264.7 cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 3-6 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

5. MRID 485701-07 "Initial Virucidal Efficacy Test Feline Calicivirus (Surrogate for Human Norovirus)" for Steriplex SD, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – April 29, 2011. Laboratory Project Identification Number 686-161.

This study, under the direction of Study Director S. Steve Zhou, was conducted against Feline calicivirus (ATCC VR-782), using CrFK cells (ATCC CCL-94) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Initial Virucidal Efficacy Test - Feline Calicivirus (Surrogate for Human Norovirus)," dated March 29, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. Two replicates per product lot were tested. The virus films were dried for 26 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of newborn calf serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 and 5% newborn calf serum. CrFK cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 7-9 days at 36±2°C in 5±1% CO_2. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

6. MRID 485701-08 "Confirmatory Virucidal Efficacy Test Feline Calicivirus (Surrogate for Human Norovirus)" for Steriplex SD, by Zheng Chen. Study conducted at MICROBIOTEST. Study completion date – April 7, 2011. Laboratory Project Identification Number 686-160.

This confirmatory study, under the direction of Study Director Zheng Chen, was conducted against Feline calicivirus (ATCC VR-782), using CrFK cells (ATCC CCL-94) as the host system. The single lot of Steriplex SD was prepared using Part A (Lot No. H202317SP) and Part B (Lot No. 8250092301). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Confirmatory Virucidal Efficacy Test - Feline Calicivirus (Surrogate for Human Norovirus)," dated March 15, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. Two replicates were tested per contact time. The virus films were dried for 30 minutes at ambient temperature. For the single lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes and 7 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of newborn calf serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES,

and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 and 5% newborn calf serum. CrFK cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 7-9 days at 36±2°C in 5±1% CO_2. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (the single product lot). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

7. MRID 485701-09 "Virucidal Efficacy Test Human Influenza A Virus (H1N1)" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – March 18, 2011. Laboratory Project Identification Number 686-146.

This study was conducted against Human influenza A virus (H1N1) (Strain A/PR/8/34; obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Human Influenza A Virus (H1N1)," dated February 25, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 17 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in Minimum Essential Medium and 1.0 µg/mL Trypsin. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

8. MRID 485701-10 "Virucidal Efficacy Test Influenza A (H1N1) Virus (2009 Pandemic strain) ("Swine Influenza Virus H1N1")" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – March 25, 2011. Laboratory Project Identification Number 686-148.

This study was conducted against Influenza A (H1N1) Virus (2009 Pandemic strain) (Strain A/California/04/09; obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The

product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Influenza A (H1N1) Virus (2009 Pandemic strain) ("Swine Influenza Virus H1N1)," dated March 2, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 31 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in Minimum Essential Medium and 1.0 µg/mL Trypsin. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

9. MRID 485701-11 "Virucidal Efficacy Test Human Immunodeficiency Virus Type 1" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – March 21, 2011. Laboratory Project Identification Number 686-147.

This study was conducted against Human immunodeficiency virus type 1 (obtained from Zeptometrix), using C8166 cells (obtained from the University of Pennsylvania) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Human Immunodeficiency Virus Type 1," dated February 25, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 18 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 21°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 with 5% fetal bovine serum. C8166 cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 9-12 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

10. MRID 485701-12 "Virucidal Efficacy Test Herpes Simplex Virus Type 1" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – March 18, 2011. Laboratory Project Identification Number 686-151.

This study was conducted against Herpes simplex virus type 1 (ATCC VR-260), using Vero cells (ATCC CCL-81) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Herpes Simplex Virus Type 1," dated February 25, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 23 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of newborn calf serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 with 5% newborn calf serum. Vero cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 5-8 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

11. MRID 485701-13 "Initial Virucidal Efficacy Test, Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)" for Steriplex SD, by Zheng Chen. Study conducted at MICROBIOTEST. Study completion date – May 12, 2011. Laboratory Project Identification Number 686-154.

This study, under the direction of Study Director Zheng Chen, was conducted against Duck hepatitis B virus (Strain LeGarth; obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes (hatchling ducks received from Metzer Farms) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. H2023 t7SP and H2023 t8SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Initial Virucidal Efficacy Test - Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)," dated February 25, 2011 (copy provided). The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at ambient temperature. Two replicates per product lot were tested. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 21°C. Following exposure, each plate was neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-

suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in L-15 complete. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 20-30 hours at 36±2°C in 5±1% CO_2 for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for an additional 9-13 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, infectious virus was assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

12. MRID 485701-14 "Virucidal Efficacy Test Avian Influenza Virus (H5N1), NIBRG-14" for Steriplex SD, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – March 25, 2011. Laboratory Project Identification Number 686-145.

This study was conducted against Avian influenza virus (H5N1) (Strain NIBRG-14; obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Using Avian Influenza Virus (H5N1), NIBRG-14" dated February 25, 2011 (copy provided). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 26 minutes at ambient temperature. For each lot of product, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in Minimum Essential Medium with 1.0 µg/mL Trypsin. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO_2. The plates were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

13. MRID 485701-15 "AOAC Use Dilution Test – Supplemental Vancomycin-resistant *Enterococcus faecium*" for Steriplex SD, by Kathryn D. Dornstetter. Study conducted at MICROBIOTEST. Study completion date – March 29, 2011. Laboratory Project Identification Number 686-158.

This study was conducted against Vancomycin-resistant *Enterococcus faecium* (ATCC 51299). Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated

by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exception: the culture was incubated for 47 hours at 37±2°C (which differs from the AOAC methods specification of 48-54 hours at 36±1°C). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 47 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC methods specification of 40±2 minutes at 36±1°C). Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. The tubes containing the activated product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC methods specification of 48±2 hours at 36±1°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one of two product lots), bacteriostasis, confirmation of the challenge microorganism, and antibiotic resistance.

Note: Antibiotic resistance of Vancomycin-resistant *Enterococcus faecium* (ATCC 51299) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0.53 mm) confirmed antibiotic resistance of Vancomycin-resistant *Enterococcus faecium* (ATCC 51299) to vancomycin. See pages 9 and 16 of the laboratory report.

14. MRID 485701-16 "AOAC Use Dilution Test – Supplemental – NDM-1 *Klebsiella pneumoniae*" for Steriplex SD, by Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – February 24, 2011. Laboratory Project Identification Number 686-141.

This study was conducted against NDM-1 *Klebsiella pneumoniae* (CI 10002; obtained from the Centers for Disease Control and Prevention, Atlanta, GA). Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exceptions: (1) the culture was initiated by inoculating a tube of Tryptic Soy Broth with 10 µg/mL Ceftazidime (which differs from the AOAC methods specification of inoculating a tube of nutrient broth or synthetic broth); and (2) the culture was incubated for 48-54 hours at 37±2°C (which differs from the AOAC methods specification of 48-54 hours at 36±1°C). Heat-inactivated horse serum was added to the culture

to achieve a 5% organic soil load. Ten (t0) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC methods specification of 40±2 minutes at 36±1°C). Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. The tubes containing the activated product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC methods specification of 48±2 hours at 36±1°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one of two product lots), bacteriostasis, confirmation of the challenge microorganism, and antibiotic resistance.

Note: Antibiotic resistance of NDM-1 *Klebsiella pneumoniae* (CI 10002) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, two antibiotic disks were added equidistant from each other on the plate. The plate was incubated and, following incubation, the zones of inhibition were measured and documented. The measured zones of inhibition (i.e., 0 mm for ceftazidime and gentamicin) confirmed antibiotic resistance of NDM-1 *Klebsiella pneumoniae* (CI 10002) to ceftazidime and gentamicin. See pages 9 and 16 of the laboratory report.

Note: The study refers to a penicillin disk in the materials, but resistance results were not provided for this antibiotic. The protocol amendment suggests that testing against β-lactam antibiotic penicillin should have been conducted.

15. MRID 485701-17 "AOAC Use Dilution Test – Supplemental – Methicillin-Resistant *Staphylococcus aureus*" for Steriplex SD, by Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – February 24, 2011. Laboratory Project Identification Number 686-143.

This study was conducted against Methicillin-Resistant *Staphylococcus aureus* (ATCC 33591). Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exception: the culture was incubated for 48-54 hours at 37±2°C (which differs from the AOAC methods specification of 48-54 hours at 36±1°C). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC methods specification of 40±2 minutes at 36±1°C). Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. The tubes containing the activated product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing

neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC methods specification of 48±2 hours at 36±1°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one of two product lots), bacteriostasis, confirmation of the challenge microorganism, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin-Resistant *Staphylococcus aureus* (ATCC 33591) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm for oxacillin) confirmed antibiotic resistance of Methicillin-Resistant *Staphylococcus aureus* (ATCC 33591) to oxacillin. See pages 9 and 16 of the laboratory report.

16. MRID 485701-18 "AOAC Use Dilution Test – Supplemental – Multi-Drug Resistant (MDR) *Acinetobacter baumannii*" for Steriplex SD, by Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – February 24, 2011. Laboratory Project Identification Number 686-142.

This study was conducted against Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605). Two lots of Steriplex **SD** were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part **B** (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exceptions: (1) the culture was initiated by inoculating a tube of Tryptic Soy Broth with 10 µg/mL Ceftazidime (which differs from the AOAC methods specification of inoculating a tube of nutrient broth or synthetic broth); and (2) the culture was incubated for 48-54 hours at 37±2°C (which differs from the AOAC methods specification of 48-54 hours at 36±1°C). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC methods specification of 40±2 minutes at 36±1°C). Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. The tubes containing the activated product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC methods specification of 48±2 hours at 36±1°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one of two product lots), bacteriostasis, confirmation of the challenge microorganism, and antibiotic resistance.

Note: Antibiotic resistance of Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with

the prepared culture in a crosshatch pattern. After crosshatching, two antibiotic disks were added equidistant from each other on the plate. The plate was incubated and, following incubation, the zones of inhibition were measured and documented. The measured zones of inhibition (i.e., 0 mm for ceftazidime and gentamicin) confirmed antibiotic resistance of Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605) to ceftazidime and gentamicin. See pages 9 and 16 of the laboratory report.

17. MRID 485701-19 "AOAC Use Dilution Test – Supplemental – *Listeria monocytogenes*" for Steriplex SD, by Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – March 29, 2011. Laboratory Project Identification Number 686-159.

This study was conducted against *Listeria monocytogenes* (ATCC 7644). Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exception: the culture was incubated for 47 hours at 37±2°C (which differs from the AOAC methods specification of 48-54 hours at 36±1°C). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 47 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC methods specification of 40±2 minutes at 36±1°C). Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. The tubes containing the activated product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC methods specification of 48±2 hours at 36±1°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one of two product lots), bacteriostasis, and confirmation of the challenge microorganism.

18. MRID 485701-20 "AOAC Use Dilution Test – Supplemental – *Escherichia coli* O157:H7" for Steriplex SD, by Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – March 29, 2011. Laboratory Project Identification Number 686-156.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots of Steriplex SD were prepared using Part A (Lot Nos. H202317SP and H202318SP) and Part B (Lot Nos. 8250092301 and 8250092302). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exception: the culture was

incubated for 47 hours at 37±2°C (which differs from the AOAC methods specification of 48-54 hours at 36±1°C). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 47 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC methods specification of 40±2 minutes at 36±1°C). Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. The tubes containing the activated product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC methods specification of 48±2 hours at 36±1°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one of two product lots), bacteriostasis, and confirmation of the challenge microorganism.

19. MRID 485701-21 "AOAC Use Dilution Test Healthcare," Test Microorganisms *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442)" for Steriplex SD, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – February 10, 2011. Laboratory Project Identification Number 686-127.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182, 01-110183, and 01-103192) and Part B (Lot Nos. 8250092301, 8250092304, and 8259091601). One lot of the activated product (i.e., Lot No. 01-103192 / 8259091601) was at least 60 days old at the time of testing. The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC methods. Heat-inactivated horse serum was added to each culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers per product lot per microorganism were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. The tubes containing the product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C. Due to the opacity of the neutralizer, the *Pseudomonas aeruginosa* subcultures were streaked onto Tryptic Soy Agar and incubated for 24±2 hours at 37±2°C after 2 days of incubation. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one product lot per microorganism), bacteriostasis (where appropriate), and confirmation of the challenge microorganisms.

20. MRID 485701-22 "AOAC Use-Dilution Test Fungicidal Test *Trichophyton mentagrophytes*" for Steriplex SD, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – February 28, 2011. Laboratory Project

Identification Number 686-137.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC method (i.e., AOAC Method 955.17). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 10-15 day old suspension of test organism, at a ratio of 20 carriers per 20 mL of suspension. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. Tubes containing the use solution were swirled after addition of the carriers, as specified in the AOAC methods. Following exposure, individual carriers were transferred to tubes of Neopeptone Glucose Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing the neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC methods. All subcultures were incubated for up to 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, inoculum counts, sterility, viability, fungistasis, neutralizer effectiveness (one of two product lots), and confirmation of the challenge microorganism.

21. MRID 485701-23 "AOAC Use-Dilution Test Fungicidal Test *Aspergillus brasiliensis*" for Steriplex SD, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – February 28, 2011. Laboratory Project Identification Number 686-138.

This study was conducted against *Aspergillus brasiliensis* (ATCC 16404). Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 16th Edition, 2006 [sic]. A culture of the challenge microorganism was prepared in accordance with the published AOAC method (i.e., AOAC Method 955.17. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 10-15 day old suspension of test organism, at a ratio of 20 carriers per 20 mL of suspension. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. Tubes containing the use solution were swirled after addition of the carriers, as specified in the AOAC methods. Following exposure, individual carriers were transferred to tubes of Neopeptone Glucose Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing the neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC methods. All subcultures were incubated for up to 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, inoculum counts, sterility, viability, fungistasis,

neutralizer effectiveness (one of two product lots), and confirmation of the challenge microorganism.

22. MRID 485701-24 "AOAC Tuberculocidal Activity of Disinfectants Initial," Test Organism: *Mycobacterium bovis* BCG, for Steriplex SD, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – May 13, 2011. Laboratory Project Identification Number 686-134.

This study was conducted against *Mycobacterium bovis* BCG (obtained from Organon Teknika Corporation). Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Confirmative in vitro Test for Determining Tuberculocidal Activity as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A culture of the challenge microorganism was prepared in accordance with the published AOAC method, with the following exception: (1) the culture suspension was diluted to achieve at least 1 x 10^4 CFU/carrier (which may differ from the AOAC method specification of diluting the culture suspension to give 20%T at 650 nm). Heat-inactivated fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) porcelain penicylinder carriers per product lot were immersed for 15 minutes in a 21-25 day old suspension of the test organism, at a ratio of 10 carriers per 15-20 mL of suspension. The carriers were dried for 30 minutes at 37±2°C. Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. Following exposure, the carriers were transferred to individual tubes of 10 mL of DE Neutralizing Broth. Tubes containing neutralizer were shaken after addition of the carriers, as specified in the AOAC method. The carriers were transferred to individual tubes containing 20 mL of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2 mL were cultured to tubes containing 20 mL of Middlebrook 7H9 Broth and 2 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were incubated for 60 days at 37±2°C. The tubes were incubated for an additional 30 days because no growth was observed after 60 days. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness (one of two product lots), and confirmation of the challenge microorganism.

23. MRID 485701-25 "Confirmatory Virucidal Efficacy Test, Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)" for Steriplex SD, by Helen Christina. Study conducted at MICROBIOTEST. Study completion date – May 12, 2011. Laboratory Project Identification Number 686-155.

This confirmatory study, under the direction of Study Director Helen Christina, was conducted against Duck hepatitis B virus (Strain LeGarth; obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes (hatchling ducks received from Metzer Farms) as the host system. The single lot of Steriplex SD was prepared using Part A (Lot No. H202317SP) and Part B (Lot No. 8250092301). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested according to a MICROBIOTEST protocol titled "Confirmatory Virucidal Efficacy Test - Duck Hepatitis B Virus

(Surrogate for Human Hepatitis B virus)," dated February 25, 2011 (copy provided). The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at ambient temperature. Two replicates were tested. For the single product lot, separate dried virus films were exposed to 2 mL of the activated product for 5 minutes at 21°C. Following exposure, the plates were neutralized with 2 mL of fetal bovine serum with 0.5% Catalase, 5% sodium bicarbonate, 10% HEPES, and 1 mM EDTA. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in L-15 complete. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 20-30 hours at 36±2°C in 5±1% CO_2 for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for 9-13 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, infectious virus was assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (the single product lot). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

24. MRID 485701-26 "AOAC Tuberculocidal Activity of Disinfectants Confirmatory," Test Organism: *Mycobacterium bovis* BCG, for Steriplex SD, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – May 13, 2011. Laboratory Project Identification Number 686-135.

This study was conducted against *Mycobacterium bovis* BCG (obtained from Organon Teknika Corporation). Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The product was tested using the AOAC Confirmative in vitro Test for Determining Tuberculocidal Activity as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A culture of the challenge microorganism was prepared in accordance with the published AOAC method, with the following exception: (1) the culture suspension was diluted to achieve at least 1 x 10^4 CFU/carrier (which may differ from the AOAC method specification of diluting the culture suspension to give 20%T at 650 nm). Heat-inactivated fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) porcelain penicylinder carriers per product lot were immersed for 15 minutes in a 21-25-day old suspension of the test organism, at a ratio of 10 carriers per 15-20 mL of suspension. The carriers were dried for 30 minutes at 37±2°C. Each carrier was placed in 10 mL of the activated product for 5 minutes at 21°C. Following exposure, the carriers were transferred to individual tubes of 10 mL of DE Neutralizing Broth. Tubes containing neutralizer were shaken after addition of the carriers, as specified in the AOAC method. The carriers were transferred to individual tubes containing 20 mL of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2 mL were cultured to tubes containing 20 mL of Middlebrook 7H9 Broth and 2 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were incubated for 60 days at 37±2°C. The tubes were incubated for an additional 30 days because no growth was observed after 60 days. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability,

neutralizer effectiveness (one of two product lots), and confirmation of the challenge microorganism.

25. MRID 485701-27 "Germicidal and Detergent Sanitizing Action of Disinfectants," Test Organisms: *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538), for Steriplex SD, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – January 31, 2011. Laboratory Project Identification Number 686-126.

This study was conducted against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538). Three lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182, 01-110183, and 01-103192) and Part B (Lot Nos. 8250092301, 8250092304, and 8259091601). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. One lot of the activated product (i.e., Lot No. 01-103192 / 8259091601) was at least 60 days old at the time of testing. [Steriplex SD is the name of the test substance after the activator is added.] The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC method, with the following exception: (1) 2 mL of phosphate buffer dilution water and sterile glass beads were used to suspend growth (which differs from the AOAC method specification of using 3 mL of phosphate buffer dilution water and glass beads). Each inoculum was standardized to yield ~10 x 10^9 organisms/mL, if required. [The AOAC method states to standardize the culture by dilution with sterile phosphate buffer dilution water to give an average of 10 x 10^9 organisms/mL.] The activated product was not tested in the presence of a 5% organic soil load. A 99-mL aliquot of each activated product was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 25°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to DE Neutralizing Broth exactly 30 and 60 seconds after the addition of the bacterial suspension. After mixing, selected aliquots of the neutralized activated product were plated in tryptone glucose extract agar. All plates were incubated for 2 days at 37±2°C (which differs from the AOAC method specification of 48 hours at 35°C). Following incubation, the colonies were counted. Controls included those for numbers count, sterility, neutralizer effectiveness (one product lot per microorganism), and confirmation of the challenge microorganisms.

26. MRID 485701-28 "Germicidal and Detergent Sanitizing Action of Disinfectants Supplemental," Test Organisms: *Escherichia coli* O157:H7 (ATCC 35150), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella typhimurium* (ATCC 13311), *Listeria monocytogenes* (ATCC 7644), *Enterobacter sakazakii* (ATCC 51239), and *Vibrio cholerae* (ATCC 14035), for Steriplex SD, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – February 24, 2011. Laboratory Project Identification Number 686-144.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella typhimurium* (ATCC 13311), *Listeria*

monocytogenes (ATCC 7644), *Enterobacter sakazakii* (ATCC 51329), and *Vibrio cholerae* (ATCC 14035). Two lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110182 and 01-110183) and Part B (Lot Nos. 8250092301 and 8250092304). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. [Steriplex SD is the name of the test substance after the activator is added.] The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC method, with the following exception: (1) 2 mL of phosphate buffer dilution water and sterile glass beads were used to suspend growth (which differs from the AOAC method specification of using 3 mL of phosphate buffer dilution water and glass beads); and (4) for *Vibrio cholerae*, Tryptic Soy Agar containing 5% defibrinated sheep's blood was used for all agar requirements. Each inoculum was standardized to yield ~10 x 10^9 organisms/mL, if required. [The AOAC method states to standardize the culture by dilution with sterile phosphate buffer dilution water to give an average of 10 x 10^9 organisms/mL.] The activated product was not tested in the presence of a 5% organic soil load. A 99-mL aliquot of each activated product was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 25°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to DE Neutralizing Broth exactly 30 and 60 seconds after the addition of the bacterial suspension. After mixing, selected aliquots of the neutralized activated product were plated in tryptone glucose extract agar. All plates were incubated for 2 days at 37±2°C. Following incubation, the colonies were counted. Controls included those for numbers count, sterility, neutralizer effectiveness (one product lot per microorganism), and confirmation of the challenge microorganisms.

27. MRID 485701-29 "Standard Quantitative Disk Carrier Test Method," Test Organism: *Clostridium difficile* (spore form) (ATCC 43598), for Steriplex SD, by Becky Lien. Study conducted at ATS Labs. Study completion date – February 17, 2011. Project Number A10833.

This study was conducted against *Clostridium difficile* (spore form) (ATCC 43598). Three lots of the activated product, Steriplex SD, were tested using the Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides (ASTM E 2197). Three lots of Steriplex SD were prepared using Part A (Lot Nos. 01-110183, 01-110184, and 01-103192) and Part B (Lot Nos. 8250092301, 8250092304, and 8259091604). The product was activated by adding the contents of a bottle of Part B into a bottle of Part A and agitating the solution for 15 seconds. One lot of the activated product (i.e., Lot No. 01-103192 / 8259091604) was at least 60 days old at the time of testing. [Steriplex SD is the name of the test substance after the activator is added.] Testing was conducted on January 21, 2011, January 25, 2011, and February 3, 2011. A culture of the challenge microorganism was prepared in accordance with ASTM method specifications. Ten (10) sterile brushed stainless steel disk carriers (1 cm in diameter; 0.7 mm thick) per product lot were inoculated with 10.0 µL of an 8 day old culture of test organism. The carriers were dried in a vacuum dessicator for at least 2 hours under ambient conditions. Each carrier was transferred, inoculated side up, to a QCT vial, to which 50 µL of the activated product was added. The carriers remained exposed to the activated product for 5 minutes at 21°C. Following exposure, 10.0 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase was added to each vial to neutralize. The contents of each

vial/carrier combination were vortexed for 45-60 seconds. As necessary, carriers were scraped with a cell scraper (while flushing the carrier surface with neutralizer) to remove any remaining inoculum from the carrier surface. The contents of each container were poured through an individual membrane filter. Each container was rinsed with saline three times, with each rinse poured through the same membrane filter. Each membrane filter was plated on CCFA-HT agar and incubated for 44-47 hours at 35-37°C. Subcultures from testing conducted on January 21, 2011 were stored for 1 day at 2-8°C prior to examination. Subcultures from testing conducted on February 3, 2011 were stored for 2 days at 2-8°C prior to examination. Following incubation, or incubation and storage, the number of survivors was enumerated. Controls included an initial suspension population, carrier population, purity, sterility, neutralization confirmation (all three product lots), and acid resistance at 2 and 5 minutes.

Note: Testing conducted from January 21-25, 2011 showed a 5.9 Log_{10} reduction for one lot of the activated product (i.e., Lot No. 01-103192 / 8259091604). The laboratory noted that one test carrier out of the 10 tested for this lot demonstrated an erratic test result of >1000 CFU recovered on the test carrier. This test carrier was inconsistent with the survivors recovered on the other 9 test carriers (geometric mean survivors of 2 CFU). Testing was repeated using a full 10 carriers to verify the original test results. All data generated are valid.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Counts (CFU/ carrier)
		Lot No. H202317SP / 8250092301	Lot No. H202318SP / 8250092302	
5-Minute Exposure Time				
485701-15	Vancomycin-resistant *Enterococcus faecium*	0/10	0/10	1.9×10^6
485701-19	*Listeria monocytogenes*	0/10	0/10	5.9×10^6
485701-20	*Escherichia coli* O157:H7	0/10	0/10	3.6×10^6

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Counts (CFU/ carrier)
		Lot No. 01-110182 / 8250092301	Lot No. 01-110183 / 8250092304	Lot No. 01-103192 / 8259091601	
5-Minute Exposure Time					
485701-16	NDM-1 *Klebsiella pneumoniae*	0/10	0/10	---	3.5×10^6
485701-17	Methicillin-Resistant *Staphylococcus aureus*	0/10	0/10	---	1.9×10^6
485701-18	Multi-Drug Resistant *Acinetobacter baumannii*	0/10	0/10	---	2.3×10^6
485701-21	*Staphylococcus aureus*	0/60	0/60	0/60	1.6×10^6

	Salmonella enterica	0/60	0/60	1/60	1.8×10^5
	Pseudomonas aeruginosa	1/60	0/60	0/60	3.6×10^6
485701-22	*Trichophyton mentagrophytes*	0/10	0/10	---	4.4×10^5
485701-23	*Aspergillus brasiliensis*	0/10	0/10	---	8.0×10^6

MRID Number	Organism	Media	No. Exhibiting Growth/ Total No. Tested	
			Lot No. 01-110182 / 8250092301 90 Days	Lot No. 01-110183 / 8250092304 90 Days
5-Minute Exposure Time				
485701-24	*Mycobacterium bovis* BCG Carrier Population: 3.6×10^5 CFU/carrier	Modified Proskauer-Beck Medium	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10
		Kirchner's Medium	0/10	0/10
485701-26	*Mycobacterium bovis* BCG Carrier Population: 3.6×10^5 CFU/carrier	Modified Proskauer-Beck Medium	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10
		Kirchner's Medium	0/10	0/10

MRID Number	Organism	Results			Plate Recovery Count
			Lot No. H202317SP / 8250092301	Lot No. H202318SP / 8250092302	
5-Minute Exposure Time					
485701-03	SARS-Associated coronavirus	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{7.00}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
485701-04	Respiratory syncytial virus	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{6.30}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{2.80}$	$\leq 10^{2.80}$	
485701-05	Poliovirus type 1	10^{-2} dilution	Infectivity	Infectivity	$10^{6.75}$ $TCID_{50}$/mL
		10^{-3} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/mL	$10^{2.50}$	$10^{2.30}$	
		Log reduction	4.25 $\log_{10}$	4.45 $\log_{10}$	
485701-07	Feline calicivirus	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{7.30}$ and $10^{8.18}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{2.80}$	$\leq 10^{2.80}$	
485701-08	Feline calicivirus	10^{-2} to 10^{-7} dilutions	Complete inactivation	---	$10^{7.30}$ and $10^{7.05}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{2.80}$	---	
485701-10	Influenza A (H1N1) virus (2009 Pandemic Strain)	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{6.75}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	

MRID Number	Organism	Results			Plate Recovery Count
			Lot No. H202317SP / 8250092301	Lot No. H202318SP / 8250092302	
5-Minute Exposure Time					
485701-13	Duck hepatitis B virus	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
485701-14	Avian influenza virus (H5N1), NIBRG-14	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{8.25}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
485701-25	Duck hepatitis B virus	10^{-2} to 10^{-7} dilutions	Complete inactivation	---	$10^{4.50}$ and $10^{4.75}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{1.50}$	---	

MRID Number	Organism	Results			Plate Recovery Control
			Lot No. 01-110182 / 8250092301	Lot No. 01-110183 / 8250092304	
5-Minute Exposure Time					
485701-06	Murine norovirus	10^{-2} dilution	Cytotoxicity	Cytotoxicity	$10^{7.00}$ $TCID_{50}$/mL
		10^{-3} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/mL	$\leq 10^{2.50}$	$\leq 10^{2.50}$	
		Log reduction	≥ 4.5 $\log_{10}$	≥ 4.5 $\log_{10}$	
485701-09	Human influenza A virus (H1N1)	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{7.75}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
485701-11	Human immunodeficiency virus type 1	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{6.93}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{2.80}$	$\leq 10^{2.80}$	
485701-12	Herpes simplex virus type 1	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{8.05}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{2.80}$	$\leq 10^{2.80}$	

MRID Number	Organism	Results			Plate Recovery Count
			Lot No. H202317SP / 8250092301	Lot No. H202318SP / 8250092302	
7-Minute Exposure Time					
485701-05	Poliovirus type 1	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{6.75}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
485701-08	Feline calicivirus	10^{-2} to 10^{-7} dilutions	Complete inactivation	---	$10^{7.30}$ and $10^{7.05}$ $TCID_{50}$/mL
		$TCID_{50}$/mL	$\leq 10^{2.80}$	---	

MRID Number	Organism / Lot No.	Test Carriers	Control Carriers	Log_{10} Reduction
		(Average Log_{10})		
5-Minute Exposure Time				
485701-29	*Clostridium difficile* (spore form); Test Date: 01/21/2011			

	01-110183 / 8250092301	<0.0	6.49	>6.4
	01-103192 / 8259091604	0.5	6.49	5.9
	Clostridium difficile (spore form); Test Date: 01/25/2011			
	01-110184 / 8250092304	<0.0	6.49	>6.5
	Clostridium difficile (spore form); Test Date: 02/03/2011			
	01-103192 / 8259091604	<0.0	6.73	>6.7

MRID Number	Organism / Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
		(CFU/mL)		
30-Second Exposure Time†				
485701-27	*Escherichia coli*			
	01-110182 / 8250092301	$<5.0 \times 10^0$	1.2×10^8	>99.999
	01-110183 / 8250092304	$<5.0 \times 10^0$	1.2×10^8	>99.999
	01-103192 / 8259091601	$<5.0 \times 10^0$	1.2×10^8	>99.999
	Staphylococcus aureus			
	01-110182 / 8250092301	$<5.0 \times 10^0$	1.2×10^8	>99.999
	01-110183 / 8250092304	$<5.0 \times 10^0$	1.2×10^8	>99.999
	01-103192 / 8259091601	$<5.0 \times 10^0$	1.2×10^8	>99.999
485701-28	*Escherichia coli* O157:H7			
	01-110182 / 8250092301	$<5.0 \times 10^0$	7.6×10^7	>99.999
		$<5.0 \times 10^0$	7.6×10^7	>99.999
	01-110183 / 8250092304	$<5.0 \times 10^0$	7.6×10^7	>99.999
		$<5.0 \times 10^0$	7.6×10^7	>99.999
485701-28	*Pseudomonas aeruginosa*			
	01-110182 / 8250092301	$<5.0 \times 10^0$	1.1×10^8	>99.999
		3.5×10^1	1.1×10^8	99.999
	01-110183 / 8250092304	1.0×10^1	1.1×10^8	99.999
		$<5.0 \times 10^0$	1.1×10^8	>99.999
485701-28	*Salmonella typhimurium*			
	01-110182 / 8250092301	5.9×10^2	9.4×10^7	99.999
		6.9×10^2	9.4×10^7	99.999
	01-110183 / 8250092304	6.6×10^2	9.4×10^7	99.999
		6.5×10^2	9.4×10^7	99.999
485701-28	*Listeria monocytogenes*			
	01-110182 / 8250092301	6.7×10^2	1.2×10^8	99.999
		7.2×10^2	1.2×10^8	99.999
	01-110183 / 8250092304	8.0×10^2	1.2×10^8	99.999
		7.2×10^2	1.2×10^8	99.999
485701-28	*Enterobacter sakazakii*			
	01-110182 / 8250092301	$<5.0 \times 10^0$	8.2×10^7	>99.999
		$<5.0 \times 10^0$	8.2×10^7	>99.999
	01-110183 / 8250092304	$<5.0 \times 10^0$	8.2×10^7	>99.999
		$<5.0 \times 10^0$	8.2×10^7	>99.999
485701-28	*Vibrio cholerae*			
	01-110182 / 8250092301	9.7×10^2	1.2×10^8	99.999
		9.0×10^2	1.2×10^8	99.999
	01-110183 / 8250092304	9.0×10^2	1.2×10^8	99.999
		8.9×10^2	1.2×10^8	99.999

†See MRID 485701-27 and 485701-28 for data for the 60-minute exposure time.

VI CONCLUSIONS

1. The submitted efficacy data support the use of the activated product, Steriplex SD, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time:

Staphylococcus aureus	MRID 48570t-21
Salmonella enterica	MRID 48570t-21
Pseudomonas aeruginosa	MRID 48570t-2t

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. The registrant's letter, dated October 28, 2011, confirmed that the efficacy data on the combined product (i.e. Steriplex SD Part A and Steriplex SD Part B) was tested at the lower certified limits (LCL). In testing against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*, at least one of the product lots tested was at least 60 days old at the time of testing. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth

2. The submitted efficacy data support the use of the activated product, Steriplex SD, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time:

Vancomycin-resistant *Enterococcus faecium*	MRID 485701-15
NDM-1 *Klebsiella pneumoniae*	MRID 485701-t6
Methicillin-Resistant *Staphylococcus aureus*	MRID 48570t-t7
Multi-Drug Resistant *Acinetobacter baumannii*	MRID 48570t-t8
Listeria monocytogenes	MRID 48570t-t9
Escherichia coli O157:H7	MRID 485701-20

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth.

3. The submitted efficacy data support the use of the activated product, Steriplex SD, as a disinfectant with fungicidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time:

Trichophyton mentagrophytes	MRID 485701-22
Aspergillus brasiliensis	MRID 485701-23

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth.

4. The submitted efficacy data (MRID 485701-24 and -26) support the use of the activated product, Steriplex SD, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time. Complete killing was observed in the subcultures of the required number of carriers against the required number of product lots. No growth was observed in the subcultures of the two extra media. Neutralizer effectiveness testing showed positive growth of the microorganism. Viability controls were positive for growth. Sterility controls did not show growth.

5. The submitted efficacy data support the use of the activated product, Steriplex SD, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load (100% organic soil load against Duck hepatitis B virus) for a 5-minute contact time (a 7-minute contact time against Poliovirus type 1):

SARS-Associated coronavirus	MRID 485701-03
Respiratory syncytial virus	MRID 485701-04
Poliovirus type 1	MRID 485701-05
Murine norovirus	MRID 485701-06
Feline calicivirus	MRID 485701-07 and -08
Human influenza A (H1N1) virus	MRID 485701-09
Influenza A (H1N1) virus (2009 Pandemic Strain)	MRID 485701-10
Human immunodeficiency virus type 1	MRID 485701-11
Herpes simplex virus type 1	MRID 485701-12
Duck hepatitis B virus	MRID 485701-13 and -25
Avian influenza virus (H5N1), NIBRG-14	MRID 485701-14

Recoverable virus titers of at least 10^4 were achieved. In studies against Murine norovirus, cytotoxicity was observed in the 10^{-2} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level. In studies against all other viruses, cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested. In studies against Feline calicivirus and Duck hepatitis B virus, the initial and confirmatory studies were performed at the same laboratory, but under the direction of different study directors. Both the initial and confirmatory studies tested two replicates per product lot. Feline calicivirus (one product lot tested) also demonstrated efficacy for a 7-minute contact time.

6. The submitted efficacy data (MRID 485701-05) do not support the use of the activated product, Steriplex SD, as a disinfectant with virucidal activity against Poliovirus type 1 on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time. A recoverable virus titer of at least 10^4 was achieved. Infectivity was observed in the 10^{-2} dilutions.

7. The submitted efficacy data (MRID 485701-29) support the use of the activated product, Steriplex SD, as a disinfectant against *Clostridium difficile* (spore form) on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time. A 6-log reduction in viable spores was reported by the laboratory. The registrant's letter, dated October 28, 2011, confirmed that the efficacy data on the combined product (i.e. Steriplex SD Part A and Steriplex SD Part B) was tested at the lower certified limits (LCL). Carrier counts were at least $>10^6$ spores/carrier.

Neutralization confirmation testing met the acceptance criterion of growth within ±1.0 $\log_{10}$ of the corresponding population control. Purity controls were reported as pure. Sterility controls did not show growth, with one exception. In testing conducted on February 3, 2011, growth was observed in the neutralizing subculture medium sterility control. Test spores showed resistance to acid for 5 minutes.

8. The submitted efficacy data support the use of the activated product, Steriplex SD, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces for a 30-second contact time (and 60-second contact time):

Escherichia coli	MRID 485701-27
Staphylococcus aureus	MRID 485701-27
Escherichia coli O157:H7	MRID 485701-28
Pseudomonas aeruginosa	MRID 485701-28
Salmonella typhimurium	MRID 485701-28
Listeria monocytogenes	MRID 485701-28
Enterobacter sakazakii	MRID 485701-28
Vibrio cholerae	MRID 485701-28

Bacterial reductions of at least 99.999 percent were observed within 30 seconds. The registrant's letter, dated October 28, 2011, confirmed that the efficacy data on the combined product (i.e. Steriplex SD Part A and Steriplex SD Part B) was tested at the lower certified limits (LCL). In studies against *Escherichia coli* and *Staphylococcus aureus*, at least one of the product lots tested was at least 60 days old at the time of testing. Neutralizer effectiveness testing showed positive growth of the microorganisms. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The proposed label claims that the activated product, STERIPLEX SD, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic load for a 5-minute contact time (7 minutes against Poliovirus type 1):

Pseudomonas aeruginosa
Salmonella enterica
Staphylococcus aureus
Listeria monocytogenes
Vancomycin-Resistant *Enterococcus faecium*
Escherichia coli O157:H7
Klebsiella pneumoniae (NDM-1)
~~Multi-Drug Resistant~~ *Acinetobacter baumannii*
Methicillin-Resistant *Staphylococcus aureus*

Mycobacterium bovis BCG

SARS-Associated Coronavirus
Respiratory Syncytial Virus
Influenza A (H1N1) Virus, 2009 Pandemic (Swine Influenza Virus)

Avian Influenza Virus (H5N1), NIBRG-14
Hepatitis B Virus
Murine Norovirus
Human Influenza A Virus
Human Immunodeficiency Virus Type 1 (HIV-1)
Herpes Simplex Virus Type 1
Norovirus (Feline Calicivirus)
Poliovirus Type 1

These claims are acceptable as they are supported by the submitted data. The Master Label must reflect the antibiotics for which resistance has been demonstrated. The claim "multi-drug resistant" in the absence of this information is unacceptable.

2. The proposed label claims that the activated product, STERIPLEX SD, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic load for a 5-minute contact time:

Trichophyton mentagrophytes
Aspergillus brasiliensis (Black Mold)

These claims are acceptable as they are supported by the submitted data.

3. The proposed label claims that the activated product, STERIPLEX SD, is an effective disinfectant against *Clostridium difficile* (spore form) on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time. This claim is acceptable as it is supported by the submitted data.

4. The proposed label claims that the activated product, STERIPLEX SD, is an effective sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces for a 30-second contact time:

Escherichia coli
Staphylococcus aureus
Escherichia coli O157:H7
Pseudomonas aeruginosa
Salmonella typhimurium
Listeria monocytogenes
Enterobacter sakazakii
Vibrio cholerae

These claims are acceptable as they are supported by the submitted data. The registrant must correct the contact time to reflect Agency standards (i.e. 1-minute minimum contact time for food contact sanitizers).

5. The following revisions to the proposed label are recommended:

- On page 4 of the proposed label (first bullet), separate the first claim into two

separate claims to clarify that the product may be used to disinfect hard, non-porous surfaces and sanitize previously cleaned, food contact surfaces. Note also that data demonstrating efficacy as a sanitizer on non-food contact surfaces was not provided.

- On page 4 of the proposed label, change "Avian Influenza A virus" to read "Avian Influenza Virus (H5N1), NIBRG-14."

- On page 4 of the proposed label, change "*Staphylococcus aureaus*" to read "*Staphylococcus aureus*."

- On page 5 of the proposed label, change "*Salmonella enteric*" to "*Salmonella enterica*."

- On page 10 of the proposed label, change "ATCC 51559" to read "ATCC 51299."

- On page 13 of the proposed label, confirm that each sanitizing application includes the following (or a similar) statement: "Pre-clean surfaces prior to sanitizing."

- On page 13 of the proposed label, change "surfaces to be disinfected" to read "surfaces to be sanitized."

- The proposed label indicates that once the solution is activated it lasts for 60 days. There is no data to support an aged solution.

- On the proposed label, remove the statement "Surrogate for Human Norovirus" behind Murine Norovirus. Currently, the Agency only identifies Feline Calicivirus as the approved surrogate.